

## **REMARKS**

### **I. Status of the Claims**

Claims 1-55 were pending at the time the Action was mailed on February 21, 2008. Claims 3-8, 11-20, 33-38 and 53-55 are presently withdrawn from consideration as being directed to a non-elected invention. Claim 1 is amended, support for which may be found in the specification and claims as originally filed. *See, e.g.*, page 12, lines 7-9 and originally filed claims 21, 40, 42 and 43. Regarding the structure of the monoterpenoid moiety in claim 1, the structure as recited in original claim 21 has been incorporated into claim 1, but with a correction to a typographical error in the structure: a methyl group has replaced a hydrogen as attached to the carbon atom to which OR<sub>3</sub> is attached. Support for this correction may be found in the specification at, for example, FIG. 39, FIG. 40 and FIG. 41. Claims 22, 24, 27, 29, 30, 31, 32, 39 and 41 are amended to reflect the amendments made to claim 1. No new matter is added by virtue of these amendments. Claims 21, 40, 42 and 43 are cancelled. Claims 1, 2, 9, 10, 22-32, 39, 41 and 44-52 are presently under consideration.

### **II. The Enablement Rejection Is Overcome**

Claims 1, 2, 9, 10, 21-32 and 39-52 are rejected under 35 U.S.C. § 112, first paragraph, as failing the enablement requirement. In particular, the Examiner asserts that the claims are not enabled for inhibiting inflammation in general.

Applicants respectfully traverse as these claims, prior to any amendment, were enabled in that a person of ordinary skill in the art could make and use the subject matter of the rejected claims from the disclosures in the application coupled with information known in the art, without undue experimentation. *See* MPEP § 2164.01. However, in an effort to advance prosecution and secure prompt allowance in this case, the claims have been amended to specify the following: "A method of inhibiting inflammation in a subject comprising administering to the subject a

monoterpene composition that inhibits NF-κB, wherein the subject has an inflammatory disease further defined as rheumatoid arthritis or inflammatory bowel disease....” Since the general condition of inflammation is no longer recited, the enablement rejection is overcome.

### **III. The Written Description Rejection Is Overcome**

Claims 1, 2, 9, 10, 23 and 39-52 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that the phrase “monoterpene” is inadequately described.

Applicants respectfully traverse as these claims, prior to any amendment, were properly described by the specification in sufficient detail that one skilled in the art could reasonably conclude that the inventors had possession of the claimed subject matter. *See* MPEP § 2163. However, in an effort to advance prosecution and secure prompt allowance in this case, the claims have been amended to incorporate the definition of a monoterpene moiety as defined in originally filed claim 21 (which the Examiner explicitly did not reject). Accordingly, the written description rejection is overcome.

### **IV. The Indefiniteness Rejections Are Overcome**

Claims 21 and 39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite with respect to improper antecedent basis for two phrases. Claim 21 has been cancelled, and claim 39 has been appropriately amended. Withdrawal of the indefiniteness rejections is respectfully requested.

### **V. The Nonstatutory Obviousness-Type Double Patenting Rejection Is Overcome**

Claims 1, 2, 9, 10, 21-32, 39-43, 46 and 48-51 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 16-21 of U.S. Patent 6,962,720. The Examiner contends that while the conflicting claims are not identical, they

are not patentably distinct from each other because the '720 patent and the rejected claims both recite methods of treating inflammation by administering a monoterpeno.

Applicants respectfully traverse. As noted above, the present claims are drawn towards treating inflammation in a subject, wherein the subject has an inflammatory disease that is further defined as rheumatoid arthritis or inflammatory bowel disease. The Examiner has provided no factual evidence to support an obviousness rejection of the amended claims. *See MPEP* § 2142 (“The examiner bears the initial burden of factually supporting any *prima facie* case of obviousness.”). Thus, no *prima facie* case of obviousness has been established. Moreover, neither rheumatoid arthritis nor inflammatory bowel disease are mentioned in the '720 patent. For at least these reasons, the obviousness rejection cannot stand.

#### **VI. The Anticipation Rejection Is Overcome**

Claims 1, 2, 89, 10, 21, 24-28, 31, 32 and 40-52 are rejected under 35 U.S.C. § 102(e) as being anticipated by Arntzen *et al.* (U.S. Patent 6,444,233).

Applicants respectfully traverse. Every element of claim 1, from which the remaining claims depend, is not taught by the '233 patent. Thus, this patent cannot anticipate the present claims. *See MPEP* § 2131. In particular, the '233 patent fails to teach the inflammatory conditions of rheumatoid arthritis and inflammatory bowel disease as recited in claim 1. For at least this reason, Applicants respectfully request that the anticipation rejection be withdrawn.

#### **VII. The Obviousness Rejection Is Overcome**

Claims 22-23, 29-30 and 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Arntzen *et al.* (WO 1999/59578).

Applicants respectfully traverse. As noted above, present claim 1 is drawn towards treating inflammation in a subject, wherein the subject has an inflammatory disease that is further defined as rheumatoid arthritis or inflammatory bowel disease. Since each of the rejected claims

depends from claim 1, the limitations of claim 1 are also limitations of the rejected claims. *See* MPEP § 608.01. Claim 1 is not rendered obvious by the '578 application: much like the obviousness-type double patenting rejection regarding the '720 patent, the Examiner has not set forth a *prima facie* case of obviousness with respect to rheumatoid arthritis and inflammatory bowel disease as recited in present claim 1. Indeed, the '578 application fails to discuss either of these conditions. For at least these reasons, the obviousness rejection cannot stand.

### **VIII. Conclusion**

This is a full and complete response to the Office Action mailed February 21, 2008. In view of the foregoing, it is respectfully submitted that each of the pending claims is in condition for allowance, and a Notice of Allowance is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-3015 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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